K071530

AUG 24 2007

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:
Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 338-8100

Contact:
Monika Campbell
Senior Regulatory Affairs Specialist

Date of Submission: June 4th, 2007

Device Identification:
Common Name:
Video Bronchoscope System

Trade Name: (optional)
Karl Storz Video Bronchoscope System

Indication: The Karl Storz Video Bronchoscope System is intended for use by physicians for diagnostic and therapeutic procedures in nasal, sinus and nasopharyngeal endoscopy, bronchoscopy, tracheoscopy and esophagoscopy and laryngoscopy. The Karl Storz Video Bronchoscope is intended to provide visualization via a video monitor.

Device Description: The Karl Storz Video Bronchoscope System includes a flexible endoscope, a CCU and a lightsource unit. The Bronchoscope is designed with distal CCD-chip technology which connects to the Karl Storz Camera Control Processor for treatment of ENT procedures.

Substantial Equivalence: The Karl Storz Video Bronchoscope System is substantially equivalent to the predicate devices since the basic features and intended uses are the same. The minor differences between the Karl Storz Video Bronchoscope System and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or general intended use of these devices.

Signed: _____
James A. Lee, Ph.D.
Manager, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 2007

Karl Storz Endoscopy- America, Inc.
c/o Ms. Monika Campbell
Senior Regulatory Affairs Specialist
600 Corporate Pointe Drive
Culver City, CA 90230

Re: K071530
Trade/Device Name: Karl Storz Video Bronchoscope System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: August 7, 2007
Received: August 9, 2007

Dear Ms. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071530

Indications for Use

510(k) Number (if known): K071530

Device Name: Karl Storz Video Bronchoscope System

Indications for Use: The Karl Storz Video Bronchoscope System is intended for use by physicians for diagnostic and therapeutic procedures in nasal, sinus and nasopharyngeal endoscopy, bronchoscopy, tracheoscopy and esophagoscopy and laryngoscopy. The Karl Storz Video Bronchoscope is intended to provide visualization via a video monitor.

Prescription Use: ___X___ OR Over-The-Counter Use: _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K071530